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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MICHAEL CRONIN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. MERCK & CO., INC., ROBERT M. DAVIS, CAROLINE LITCHFIELD, and DEAN Y. LI, Defendants.	Case No. 2:25-cv-01208 **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Demand for Jury Trial

Plaintiff Michael Cronin ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Merck & Co., Inc. ("Merck" or the "Company")

with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Merck's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Merck securities between February 3, 2022, to February 3, 2025, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning Merck's expected revenue of $11 billion from sales of Gardasil by 2030. Defendants' statements included, among other things, confidence in Merck's purported ability to utilize successful consumer activation and education efforts on the benefits of Gardasil in order to drive demand and capitalize on eligible populations for vaccination, resulting in confidently optimistic reports and forecasts of Gardasil's growth in China.

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating materially false and misleading statements and/or concealing material adverse facts concerning the true state of Gardasil's demand in China; notably, that Merck lacked visibility into demand for Gardasil in China among eligible and otherwise targeted populations, resulting in the inflated inventory of its distributor, Zhifei. Such statements absent these material facts caused Plaintiff and other shareholders to purchase Merck's securities at artificially inflated prices.

4. Investors began to question the veracity of Defendants' public statements on July 30, 2024, during Merck's earnings call following a same day press release announcing its second quarter fiscal year 2024 earnings. In pertinent part, Defendants announced a significant reduction in Gardasil vaccinations, resulting in inventory levels at Merck's distributor in China to climb above normal levels. As a result, Defendants announced that its shipments of Gardasil to China may fall below contracted levels for 2024, yet they remained confident in their long-term projections both in the region and globally.

5. Investors and analysts reacted immediately to Merck's revelation. The price of Merck's common stock declined dramatically. From a closing market price of $127.78 per share on July 29, 2024, Merck's stock price fell to $115.25 per share on July 30, 2024, a decline of about 9.78% in the span of just a single day.

6. Notwithstanding the second quarter's disclosures, Merck and the Individual Defendants continued to mislead investors. Defendants continued to create the false impression that they possessed reliable information pertaining to the underlying issues surrounding the purported demand slowdown for Gardasil in China, while also minimizing the risks associated with competition and macroeconomic fluctuations. During the October 31, 2024, earnings call, Defendants continued to mislead investors with repeated statements of confidence in Gardasil's growth in China, both in the existing eligible population of women and the planned expansion following approval for male vaccinations, particularly as they related to Merk's ability to achieve $11 billion in worldwide Gardasil sales by 2030. Defendants further positively highlighted Merck's efforts to assist Zhifei with resources for promotional and educational efforts to bolster Gardasil sales while maintaining reduced shipping levels. At the time, Defendants touted the success of such efforts which had resulted in the reduction of overall channel inventory levels. Pertinently, Defendants made no indication additional shipping cuts to Zhifei would be necessary.

7. The full truth finally emerged on February 4, 2025, when Merck announced it would no longer achieve the long-forecasted $11 billion in sales of Gardasil by 2030, as it would cease shipments of Gardasil to China "through at least midyear" to facilitate a "rapid reduction of inventory." Defendants claimed this was

necessitated by the continued over-inflation of overall channel inventories as demand in China for Gardasil had "not recovered to the level we had expected."

8. Investors and analysts again reacted promptly to Merk's revelations. The price of Merck's common stock declined dramatically. From a closing market price of $99.79 per share on February 3, 2025, Merck's stock price fell to $90.74 per share on February 4, 2025, a decline of more than 9% in the span of just a single day.

JURISDICTION AND VENUE

9. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

10. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

12. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Merck is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

13. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

14. Plaintiff purchased Merck common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Merck is attached hereto.

15. Merck & Co., Inc. is a New Jersey corporation with its principal executive offices located at 2025 East Scott Avenue, Rahway, NJ 07065. During the Class Period, the Company's common stock traded on the New York Stock Exchange (the "NYSE") under the symbol "MRK."

16. Defendant Robert M. Davis ("Davis") was, at all relevant times, the President and Chief Executive Officer of Merck. Davis previously served as a Director of Merck and was appointed Chairman as of December 1, 2022.

17. Defendant Caroline Litchfield ("Litchfield") was, at all relevant times, an Executive Vice President and the Chief Financial Officer of Merck.

18. Defendant Dean Y. Li ("Li") was, at all relevant times, an Executive Vice President of Merck and the President of Merck Research Laboratories.

19. Defendants Davis, Litchfield, and Li are sometimes referred to herein as the "Individual Defendants." Merck together with the Individual Defendants are referred to herein as the "Defendants."

20. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Merck's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

21. Merck is liable for the acts of the Individual Defendants, and its employees under the doctrine of respondeat superior and common law principles of

agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

22. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to Merck under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Company Background

23. Merck is a global healthcare company that operates through two segments, Pharmaceutical and Animal Health, with a significant focus on prescription medications.

24. In the Pharmaceutical segment, Merck sells both therapeutic and preventative agents, generally by prescription, to physicians, wholesalers, distributors, and government entities for appropriate treatment and distribution to patients.

The Defendants Materially Misled Investors Concerning

Merck's Revenue Outlook for Gardasil

February 3, 2022

25. On February 3, 2022, Defendants conducted an earnings call corresponding to their fourth quarter and full-year fiscal 2021 results where they first forecasted $11 billion in Gardasil sales by the year 2030, stating, in pertinent part:

> [W]e have many important franchises beyond oncology that we expect can drive durable growth into the next decade, including GARDASIL, which we believe can potentially double by 2030

26. Notably, pursuant to Merck's 10-K, filed on February 25, 2022, Gardasil earned $5.673 billion in fiscal 2021.

April 28, 2022

27. On April 28, 2022, Defendants published their first quarter fiscal year 2022 results and conducted a corresponding earnings call. During the call, Defendants touted the success of Gardasil and its future prospects, stating, in pertinent part, the following during their prepared remarks:

> Global demand for GARDASIL remains strong and growth will benefit from increased supply as a result of the significant investments we are making to expand manufacturing capacity
>
> . . .
>
> Our vaccines portfolio again delivered excellent performance led by GARDASIL, which increased 60% to $1.5 billion. Outside the U.S., significant growth was driven by strong underlying demand across key

> geographies, particularly China as well as increased supply. In the U.S., sales increased due to the timing of CDC purchases.
>
> Global demand for GARDASIL remains robust, supported by strong clinical and real-world data as well as efforts to increase the recognition of GARDASIL as a vaccine that can help prevent certain HPV-related cancers in both females and males.

(Emphasis added).

28. A question-and-answer portion of the call following during which Defendants reiterated their expectation to achieve $11 billion in Gardasil sales by 2030 in the following pertinent exchange:

> <Q: Colin Nigel Bristow – UBS Investment Bank – Analyst> Congrats on the quarter. And I also wanted to say all the best to Roy. It's been really great working with you, and also congrats to Eliav. ***So I just wanted to piggyback on a GARDASIL question. Could you maybe just give us a little more detail on how you expect the GARDASIL supply to increase?*** And then maybe just help us think through what is the supply/demand mismatch right now? Some of your prior comments suggested that there may not be such. But I know you said supply has been an issue over the past sort of couple of years. So would love to get some expanded thoughts there.
>
> <A: Caroline Litchfield> Thank you for the question. This is Caroline. So let me start first with the supply/demand. There is significant demand for GARDASIL. This cancer-preventing vaccine in the HPV area has only reached today 9% of the global eligible population. So there is significant runway ahead of us to protect lives and to drive growth for Merck. ***Indeed, we've stated that we expect the revenue in year 2030 to be double the $5.7 billion we achieved in 2021***. So we have significant opportunity ahead of us.
>
> ***In order to achieve that opportunity, we are building new facilities that will be coming online from 2023, 2024 and 2025. So we're going to have a step-up in the level of supply to the market that will happen over that period***.

> Specific then to this year, we will see a continuation of the supply into the market as we did in 2021, albeit not quite at the same step-up that we achieved in 2021. ***So we remain really confident in our ability to drive strong growth for GARDASIL both in 2022 and the years to come.***

(Emphasis added).

January 9, 2023

29. On January 9, 2023, Defendants presented at the 41st Annual J.P. Morgan Healthcare Conference and pertinently discussed their expectations for Gardasil, stating:

> As you look at the durable growth drivers, what's important as you think about our vaccines business and our Animal Health business, these are very much annuity-like businesses with stable growth. And in both cases, we have a growing pipeline. So as you see, what we showed to be nice and robust growth across both, we expect that to continue into the long term. We've talked about starting with the vaccines business, ***which is really anchored in our product, GARDASIL, that, that product will continue to grow meaningfully***. And in fact, we expect it to more than double off of 2021 sales. ***So that -- if you look forward, what that means is growth in excess of $11 billion by 2030.***

(Emphasis added).

30. Defendants elaborated further on this goal during the question-and-answer portion that followed:

> <Q: Christopher Thomas Schott – JPMorgan Chase & Co – Senior Analyst> Great. Rob, on GARDASIL, this product clearly has exceeded expectations pretty consistently here. I know you talked about $11 billion-plus in 2030 sales. What do we need to do to bridge from where we are today to get to that peak sales level? And I guess part of

my -- the second piece of that would be -- is that peak? Or is that just -- can this actually get even much larger than that given the...

<A: Robert M. Davis> Well, if you look at where we are in the journey, obviously, it starts with a growing recognition, which I think is now really taking hold that as Dean said, this is a cancer vaccine, which is important. So we're going to continue to drive it. But if you look across the global population, it's still -- there's still a huge unmet need, and it's pretty underpenetrated. The focus areas, how can we drive geographically to drive for greater reach, continue to drive for gender neutral. There still is a situation and underappreciation that it's not only protecting the female, you need to get the male protected because that brings protection for the female. But increasingly, people are recognizing there are a lot of cancers that affect the males as well, head and neck and others, that it's important that you bring both. So we're going to continue to drive for gender neutral.

And then increasingly, we're now, as we start to bring online additional capacity, we can start to drive also into the mid-adult population. We've obviously been limited to trying to do it more in the pediatric setting because we were limited in what we had. As we go to having an unconstrained situation, we'll be able to go more fully across all of these areas. And if you look at where we are today, actually in 2023, we're bringing online 2 new bulk facilities. Those will be ramping up between 2023 and 2025. ***So as we get to '25, we will be unconstrained in our ability to drive global demand.***

In the meantime, we've shown we can drive productivity in our existing facilities. That's why we've been able to drive the growth we've had. ***And I'm confident you're going to see us grow. We're very confident in hitting the $11 billion number. I don't want to get into projections beyond that, but let's just say that the global need is still significant, and we're committed to trying to address it.***

(Emphasis added).

April 27, 2023

31. On April 27, 2023, Defendants conducted and earnings call corresponding to their first quarter fiscal year 2023 results. During the call, Defendants discussed a plan to accelerate shipments to Zhifei, Merck's distribution partner in China, stating in pertinent part:

> Our vaccines portfolio delivered excellent growth led by GARDASIL, which grew 43% to $2 billion. Performance was driven by strong demand in major ex-U.S. markets particularly China as well as increased supply. ***Growth also benefited from an acceleration of shipments to China from the second half to the first half of the year to ensure the availability of product to meet heightened demand following the approval of the expanded indication of GARDASIL 9 for girls and women, 9 to 45 years of age***
>
> . . .
>
> Finally, we are confident in our ability to drive strong growth of GARDASIL, particularly in international markets. We are well positioned to protect many more people from HPV-related cancers now and over the long term. And given the strong global demand for the vaccine, we see an acceleration of growth for GARDASIL in the full year 2023 relative to 2022 but not quite at the same level of growth achieved this quarter.

(Emphasis added).

32. Defendants elaborated further in the following pertinent exchange during the question-and-answer portion of the call:

> <Q: Timothy Minton Anderson – Wolfe Research, LLC – Managing Director of Equity Research> I have a question on GARDASIL in China. So the GFA contract from your Chinese distributor published a couple of months ago shows really big purchase orders consistently for

> the next few years and it kind of trails off and declines. And it's interpreted literally it could suggest there was kind of a bolus effect going on where growth isn't linear. It goes up for a while, then it contracts as you work through warehouse patients. Is that how we should think about the longer-term uptake of GARDASIL in that particular market that it might not be linear?
>
> <A: Robert M. Davis> Yes. Just -- ***so if you look at the GFA contract, it's important to understand that the levels put in that contract are minimums***. And in fact, we have shown and our history has been that actually we have supplied well over the minimum. So I wouldn't interpret that as the literal forecast of the business in China because there's opportunities with the expanded age cohorts as we continue to drive penetration in what is still a large unmet population, there is opportunities to do better than what's in that contract. And if history isn't indicative of the future, we would expect to see that move forward. ***So I would not interpret that as implying a decline in GARDASIL in China over the coming years.***

(Emphasis added).

October 26, 2023

33. On October 26, 2023, Defendants conducted an earnings call for their third quarter fiscal year 2023 results. During the question-and-answer segment, Defendants pertinently discussed Gardasil's growth opportunities at length in response to the following inquiry:

> <Q: Christopher Thomas Schott – JPMorgan Chase & Co. – Senior Analyst> I just had a question on GARDASIL. We've seen obviously some very impressive growth over the past few years. But looking ahead, I'm just interested in how much more opportunity for -- you see for this franchise to ramp from here. So maybe just elaborate a little bit more on what are the kind of unmet needs at this point? Where is the biggest opportunity to continue to kind of roll out the product? And just ultimately, how much larger can this franchise become over time?

<A: Robert M. Davis> Yes. Chris, no, I appreciate the question. So one, I would say we feel very proud of GARDASIL has -- strength of this business. And the fact that people increasingly recognize that we can fundamentally do what's the most important, which is prevent cancer, prevent cervical cancer, increasingly prevent certain head and neck cancers if we can get people fully vaccinated. So the fact that you are starting to see that progress is important.

But as we look at the business going forward, I would start by saying we remain very confident that this is a business that's going to continue to grow and that we will achieve the expectation we've communicated of over $11 billion in revenue by 2030. So nothing has changed in how we see the business. ***As you know, we've made significant investments in manufacturing capacity***. And from that perspective, now we're well positioned. We've brought on our 2 sites, and they're ramping now. And so we're doing quite well from that perspective.

And then as far as the opportunities that exist to potentially continue to drive even beyond what we just discussed, really, I would put in 3 buckets. And our ability to achieve that objective and then potentially exceed that objective really come down to these 3 variables.

And first and foremost, while we've had great penetration in the developed world, a huge opportunity still exists in the low and middle income markets. And I can tell you, we have a focus and an intention to drive this business into the low and middle income markets. Obviously, that's going to require us to continue to drive down our manufacturing costs, which we have plans to do. And I have confidence that we will do. And to think about lower price points, but that said, that will be a meaningful incremental revenue as we achieve that over time.

And then as you look at the established markets, there still is a large population to address. Obviously, to date, we've been driving largely through public vaccination programs outside the United States, in the United States through the nationalization program, primarily aimed at young women -- young girls. Increasingly, the opportunity to go to broader age cohorts as we think about going now to people age 45, that

ability to move into the mid-adult segment is a real opportunity in the United States.

It continues to be a driver of growth. It's increasingly going to be a growth driver in Europe, and it is currently an important part of why we're driving growth with the recent expansion we got in China, and there are more markets to come. So as we look at that, that's going to be another lever of growth.

Obviously, the difference here is this requires consumer activation. That takes commercial investment and a lot of heavy lifting. We've demonstrated we can do it like we've started to do in China and as we're starting to do in the United States. But it is going to take a lot of work and investment, and we're committed to doing that. So that's another variable that we look at.

And then lastly, this is still largely seen as a female vaccine. We only -- I think it's only 70 markets have gender-neutral approvals. And even in the markets that do have it, particularly as you look at markets like Europe, there still is a real opportunity to increasingly bring people to understand that this is not just a female cancer vaccine, it is a gender-neutral cancer vaccine. And with the growing incidence of head and neck cancers, which is primarily a male-dominated cancer, we do see real opportunity to continue to push and drive, both getting more markets to gender-neutral and in the markets where we have those approvals drive vaccination rates up. ***And probably one of the bigger near-term opportunities is to get gender-neutral approved in China, which is an opportunity.***

So across all of those, there's opportunities and potential. It's a heavy lift. I don't want to indicate that it's going to be easy. And we're going to invest behind it. But that really will determine ultimately, our success across those variables will determine the success we see long-term with this franchise. But maybe Dean or Caroline, anything you would add?

<A: Dean Y. Li> Yes. I would just emphasize 2 points, one, directly related to what you said. This is a highly effective vaccine to prevent women's cancer, cervical cancer. And that is something that everyone recognizes, but ***the gender-neutral part is really important. And at MRL, we're advancing studies and filings in relationship to make***

> ***sure that as many places that can adopt gender-neutral can be in that position to do gender-neutral*** . . .

(Emphasis added).

February 1, 2024

34. On February 1, 2024, Defendants held an earnings call to discuss Merck's fourth quarter fiscal year 2023 results. Defendants briefly touted Gardasil's growth in the fourth quarter, noting the "Vaccines portfolio delivered excellent growth led by GARDASIL, which increased 27% to $1.9 billion, driven by global demand, ***particularly in China***" (emphasis added).

35. During the question-and-answer segment, Defendants discussed Gardasil's growth and revenue opportunities in China, in pertinent part, during the following exchange:

> <Q: Adam Jolly – Wolfe Research, LLC – Research Analyst> This is Adam on for Tim. On GARDASIL, a 2-dose regimen was recently approved in China. We're wondering if that poses a revenue problem. Potentially, it doesn't, if it just means that more supply gets spread out across more people, and Merck ends up selling just as many doses in total. Can Merck share its perspective here?
>
> <A: Robert M. Davis> No, Adam, thanks for the question. ***So there's actually been Chinese competitors with an offering for some time actually in the Chinese market. And that market is large. We continue to believe in the eligible cohorts in just the urban females***, which is the Tier 1 to Tier 3 cities, is about 200 million -- a little over 200 million women. ***And so of that, we think probably about 30% have actually received vaccination. So you're still looking at 120 million, 130 million eligible population.***

> ***As we look at this and as we've seen over time, we continue to be very competitive. We're maintaining a vast majority of share in the private market. And really, you're seeing most of the local competitors go to the lower-tier cities and to a different population than we've been targeting. So that does not change our view of the growth potential in China long term***. Obviously, we will continue to face competition there, and we are positioning ourselves to continue to succeed there. But the approval you're talking about is not changing our view.
>
> <A: Caroline Litchfield> The only thing I add, if I may, is we have significant opportunity to protect further females in China. ***At the end of 2023, we also submitted to the regulatory authorities our data on GARDASIL for males. So we're hopeful to introduce that in the Chinese market in the future.***

(Emphasis added).

April 25, 2024

36. On April 25, 2024, Merck issued a press release reporting first quarter fiscal year 2024 results. During the earnings call that followed, Defendants disclosed that they anticipated a reduction in Gardasil shipment to China during the second quarter due to the acceleration in shipments during the year-ago quarter, stating in pertinent part:

> ***Our vaccines portfolio delivered strong growth, led by GARDASIL, which increased 17% to $2.2 billion, driven by global demand. Sales also benefited from the timing of shipments in China*** and CDC purchasing patterns in the U.S. VAXNEUVANCE sales grew to $219 million, driven by continued uptake of the pediatric indication in the U.S. and ongoing launches in international markets, particularly in Europe. In the U.S., VAXNEUVANCE sales also benefited from CDC purchasing patterns. Sales in our Animal Health business grew 4%. Livestock sales growth was driven by price actions as well as demand

> for swine and poultry products. Companion animal growth reflects price actions.
>
> . . .
>
> As you consider your models, there are a few items to keep in mind. The increase in our sales guidance is driven by the strong performance across our current product portfolio, led by KEYTRUDA, which continues to experience growth from additional indications and patient demand. ***For GARDASIL, second quarter ex U.S. growth will be adversely impacted by shipment timing to China. This year, we expect more evenly distributed quarterly shipments to China***. Recall, in 2023, we accelerated shipments from the second half to the first half of the year, which primarily impacted the second quarter. ***Over the near and long term, we remain confident in our ability to protect many more people from HPV-related cancers and drive growth of GARDASIL.***

(Emphasis added).

37. Defendants elaborated further on the near-term headwind to distribution during the question-and-answer portion of the call in the following pertinent exchange:

> <Q: Christopher Thomas Schott – JPMorgan Chase & Co. – Senior Analyst> Just a couple of GARDASIL questions. You're pointing to a more evenly distributed China sales this year, and it seems like a tougher 2Q comp. But can you just directionally talk about growth for GARDASIL more broadly for the year? I guess the heart of it is still a healthy growth asset for you this year. And the second one on GARDASIL is if we were to move to a single dose of GARDASIL-9, what does that mean commercially and from a sales perspective for the franchise?
>
> <A: Caroline Litchfield> Chris, it's Caroline. ***So in terms of the phasing of GARDASIL, as you pointed out, during 2023, we saw in China an acceleration of the shipment from the second half of the year to the first half of the year, specifically to the second quarter. What that's done is it's provided an actual tailwind to revenue growth***

> ***in the first quarter for China, but it will provide a headwind more significant in the second quarter. And that's what we've called out.***
>
> As we look at overall growth for GARDASIL, given where we are with the level of vaccinations across the world, given the manufacturing that we have been scaling up, ***we're confident in our ability to continue to drive growth during 2024. And in 2025, we will see our manufacturing capacity unconstrained so enabling us to further supply and support the market.***
>
> As we've talked in the past, our opportunities for growth are significant as we look to continue to improve on adolescent vaccination rates, as we look to improve upon gender-neutral vaccinations, as we look to really activate the mid-adult segment, but increasingly get to the lower-income and middle-income markets, which will come at a different price point.
>
> ***As we sit here today, continue to be confident in the outlook for GARDASIL over both the near and the long term.*** As we look at the possibility of a single dose of GARDASIL, the study that we are conducting will be a comprehensive study and will take some time to unfold. ***What we're seeing in the marketplace currently is where certain low-income markets are implementing a single-dose regimen, they are also increasing the numbers of people they are vaccinating by broadening the age cohort or also opting to vaccinate males at this stage. We'll have to be long term how the data plays out with regards to a single dose to ensure that we will price our vaccine based on the benefit that we're bringing and we vaccinate as many people in the world that we can.***

(Emphasis added).

38. The above statements in Paragraphs 25 to 37 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information pertaining to Merck's projected revenue outlook and anticipated growth of Gardasil while also minimizing risk from competition and drug approval

developments, such as China's approval to shift Gardasil to a 2-dose regimen. In truth, Merck's optimistic reports of growth, claims of successful consumer activation and education in China, overall ability to drive demand, and efforts to downplay the impact of competition on Gardasil fell short of the reality; the Company's ability to push Gardasil in China had materially diminished.

Merck Reveals Reduced Gardasil Outlook for the Remainder of Fiscal Year 2024 During its Second Quarter Earnings Report

July 30, 2024

39. On July 30, 2024, Defendants announced significant and allegedly sudden setbacks to Gardasil sales in China from Zhifei to purchasers down the distribution chain during their second quarter fiscal year 2024 earnings call, stating in pertinent part:

> Our vaccines portfolio delivered solid growth. GARDASIL sales increased 4% to $2.5 billion. In the U.S., sales benefited from price as well as demand and favorable CDC purchasing patterns. Outside the U.S., higher demand across many international markets was partially offset by the timing of shipments to China
>
> . . .
>
> For GARDASIL, over the past few years, we've benefited from extremely strong demand in China, including from the expanded indication for GARDASIL 9 to the 9- to 45-year age cohort in late 2022. ***In the second quarter, however, there was a significant step-down in shipments from our distributor and commercialization partner, Zhifei, into the points of vaccination compared with prior quarters, resulting in above normal inventory levels at Zhifei***. We are working closely with them to more fully understand the dynamics that caused this

> change. As we learn more, we will assess future shipments to our partner and work to bring their inventory back to more normal levels. ***If shipments from Zhifei into the points of vaccination do not increase, it is likely that we will ship less than our full year 2024 contracted doses by the end of this year.***
>
> We believe the opportunity in China remains very attractive as there are more than 120 million females in the addressable population living in Tier 1 to Tier 5 cities who have not yet received the protection of an HPV vaccine. As we said before, it will take increasing efforts to educate and activate the next wave of patients. ***Together with Zhifei, we are focused on and committed to investing in additional resources and patient education on the value of GARDASIL given the important benefit it provides. We also look forward to the potential approval for males, which we believe represents a meaningful opportunity.***
>
> More broadly, ***we remain confident in the opportunity for GARDASIL globally based on the protection it provides against HPV-related cancers and low immunization levels overall, and continue to believe we will achieve sales of over $11 billion by 2030***. Our initial launch of WINREVAIR is having a positive impact for patients. We are very pleased with its performance and look forward to supporting more patients in the U.S. and across the globe.

(Emphasis added).

40. During the question-and-answer portion of the call that followed, Defendants elaborated upon the setbacks disclosed in their prepared remarks while remaining confident in their long-term projections for Gardasil as follows:

> <Q: Christopher Thomas Schott – JPMorgan Chase & Co. – Senior Analyst> Congrats on the progress. I just want to kick off with just a question on GARDASIL dynamics in China. Maybe just a two-part question here. First, can you quantify what percent of your international sales are coming from China? And just any additional color on what drove the step-down in 2Q? I'm just trying to get my hands around this. And maybe as part of that, the 2024 guidance update, is the potential for shipments to come below the 2024 contracted doses now reflected

in that guidance? Or would that represent an incremental headwind to numbers to the extent that played out?

<A: Robert M. Davis> Great. Thanks, Chris, and thanks for the question. And I'll maybe take the first part and then ask Caroline to comment on guidance. To your question, China represents about -- for GARDASIL of about 60% to 70% of the numbers. So that kind of gives you a sense of it. But maybe to give some context on what we saw in the quarter, and as we look to the full year and where we see things going. So let me start maybe by talking a little bit about the dynamics.

The opportunity that exists for GARDASIL in China remains very attractive with more than 120 million eligible females in China yet to be protected against HPV, which represents about 60% to 70% of the eligible population. And I think we all recognize the benefits of protection against HPV-related disease is clear and importantly, aligns with China's Healthy 2030 initiative. So the underlying support, we continue to believe is there.

In addition, we have filed for the male indication, which has been accepted and represents another significant opportunity. So as we think about China, I just want to set the context because I think it's important to understand, we continue to have a very meaningful opportunity in the China market. What's unclear to us and what we're trying to understand is that during the second quarter, we saw a significant step-down in shipments from Zhifei to the points of vaccination.

The reductions during the second quarter was surprising, and I would point out was a meaningful departure from prior trends we've seen both throughout really all of 2023 and into the first quarter of 2024. So as we look at this, we're wanting to understand what would cause the trend break we saw. And I can tell you what we know as of now is we believe there could be multiple factors that may be contributing to this dynamic, and ***we're working closely with our partner to try to tease out what exactly is happening.***

But overall, the data we track indicates that the whole HPV market in China experienced this step-down. So this is not a Merck-specific event. And importantly, we see the market share for GARDASIL as stable or

actually increasing right now in the marketplace. ***We don't believe this step-down, therefore, represents any change in the competitive dynamic, and GARDASIL remains by far the market leader.*** We do believe, however, that based on the intelligence we've gathered, activity in the HPV vaccine area has been recently impacted by China's anti-bribery and anti-corruption drive which, as you know, started really last year.

And up to that point, we really haven't seen much impact, but we do believe we are starting to see it now. And this is really driven by the fact that in the health care industry, there has been, as a result of this, a reduction in scientific engagement, primarily in the CDC within China and fewer immunizations. So we need to tease that out more. ***And in addition, we did see reduced levels of promotional support for HPV vaccination at the same time that our distribution partner, Zhifei, broadened its portfolio.*** So we'll need to get more into that.

But obviously, we have a very strong relationship with Zhifei, and ***we already have started to put in place a robust plan to invest in increased promotional efforts really designed to drive awareness, education and activation of the remaining female opportunity. And this includes both resources at Zhifei and more selling resources and promotional resources as well as promotional resources being deployed directly from Merck. So as we look forward, we'll have to see how all of these activities impact shipments to the point of vaccination.*** And as we learn more, we'll assess future shipments to China with our partner. So hopefully, that gives you a sense of what we're seeing.

But I just would reiterate one other point. And that's, that as we look to the long term, given both the opportunity in China, I mentioned for the 120 million remaining females as well as the potential for the male indication, outside of China, we saw double-digit growth across all regions in the quarter. So we continue to be on track, doing well and driving growth in this important vaccine. And that's why you heard Caroline in our prepared comments reiterate our confidence in the $11 billion number by 2030, even taking into account what we saw China happening in China this quarter.

So with that, maybe I'll turn it over to Caroline and she can address your guidance-specific question. Caroline?

<A: Caroline Litchfield> ***Thank you, Rob. So Chris, in terms of our guidance, we've assumed a range of scenarios, from providing the fully contracted 2024 doses during this year to providing something less than that. If I anchor to the midpoint of our guidance, we have been measured in assuming a scenario that has less than the contracted 2024 GARDASIL doses shipped to China***. And even with that, we were able to raise our guidance at the midpoint by $200 million. And that's really as a result of the underlying momentum that we have in the rest of our business, including oncology, with KEYTRUDA and WELIREG. It includes Animal Health with the launch of BRAVECTO in injectable as well as the acquisition of the Elanco aqua business. And we remain confident in our outlook for WINREVAIR and the opportunities to drive patient impact and growth consistent with our high expectations.

. . .

<Q: Umer Raffat – Evercore ISI Institutional Equities – Senior MD & Senior Analyst of Equity Research> Can I just dial down the GARDASIL point just a little more? Rob, I know you mentioned there's an anti-bribery, anti-corruption drive going on in China, which started last year. But it also feels like some of the shipment delays are happening, perhaps a few months ahead of potential competition hitting the market as well. So could you speak to whether there's any future contracting happening and whether your long-term price integrity will stay intact on GARDASIL in China?

<A: Robert M. Davis> Yes. No, thanks for the question. ***So everything we're seeing in the marketplace, I would just reiterate, would point to dynamics that we don't see the competition, the future potential competition***. I think you're referring to the fact that we very well could see a 9-valent sometime next year come into the marketplace. So I don't believe from anything we've heard in the marketplace, from competitive intelligence as well as what we're hearing from Zhifei that, that is what's happening here.

As we look forward, and Caroline can comment specifically, ***we have always expected that as we see the peak move through from the indication we got for the expansion of the age cohort, that you would***

see a flattening out over time of the demand in China. And then that, for women, specifically, and then we would bring on the male indications that should allow us then to continue to drive the business forward from there. Nothing has changed in that dynamic in what we're seeing right now. So as we look forward, our belief in China being a significant contributor is unchanged.

But I'll let -- maybe Caroline can speak specifically as we're thinking about some of the guidance around how we think about next year.

<A: Caroline Litchfield> ***So what I would add is we have always contemplated that we would have a 9-valent competitor within the Chinese market. As such, the current contracted doses with Zhifei for 2025 are less than what the contract is for 2024***, as we would expect to participate in that market but understand a competitor would likely gain share in that market. ***We also, though, as we said in the prepared remarks, has the potential opportunity of a male launch in China***. And we are hopeful for an approval with GARDASIL 4 and 9 by first half of next year, and be coming to the market at that stage. ***So we are confident that China will remain an important part of our GARDASIL business as we move forward and, more importantly, are confident in the opportunity to drive GARDASIL longer term, the $11 billion that we've stated.***

. . .

<Q: Timothy Minton Anderson – Wolfe Research LLC – Managing Director of Equity Research> Just going back to GARDASIL. I know you're reiterating your $11 billion figure, at least $11 billion in 2030. The shape of the curve over that time in China specifically, which is only a part of that number, are there likely to be periods where year-on-year sales actually contract beyond 2024 and the inventory issue? Because it does seem like pricing is really going to be a risk here, the way pricing works with vaccines in China. And some of these other offsetting indications like males are going to take time to launch. So it seems like there may be periods there where you could have year-on-year declines in sales over the next, let's say, 5 or 6 years. So if you could just describe the shape of that curve, please?

<A: Robert M. Davis> Yes. Sure. ***So as we look at it, we do expect you will see a flattening of the curve, as we see the female indication be more fully penetrated. Obviously, more to go there, given what we believe is still the addressable population. And then it will ramp back to growth as the male population comes on in full. So that is what we're expecting to happen.***

And on the pricing point, I think it's just important to understand the way this market works and how we operate in the market. We sell into Zhifei. Zhifei then is responsible for doing the bidding with the provinces, and actually then determining ultimately that end sale to the point of vaccination. ***As we look forward, I think it's important to understand that GARDASIL as we think about the addressable population, we continue to believe, will be a highly sought-after vaccine even in the face of competition.*** And we're dealing in an overall population when we quote the 200 million total females, of which we would say we're 30% to 40% penetrated today. That's really in the Tier 1 to 5 cities that we think can afford a cash pay market. ***The total population accessible in China is much bigger.***

And so I don't think we should assume we're all competing for that small slice. There's a much bigger slice we've chosen not to go for that bigger piece because obviously, we can't get into the local vaccination program because we don't produce GARDASIL in China. Our competitors will be able to do that. So I think I would just caution all to not view it as a zero-sum game.

I think there's still a market expansion opportunity in China that will benefit both us and the competitors. ***And frankly, the other thing we have to see is how quickly will the male indication be given to others beyond us. We believe there's a chance we could be [sitting alone with that] as well. So the dynamics need to play themselves out.*** But I think we need to first understand is what we're seeing in the quarter specific, a short-term event or something else.

And that's still not clear because I would just point that the trend break was pretty significant. ***It's not what we've seen in any of the markets that you would expect. And that's why we're a little hesitant to say this is just demand in China.*** And also, I would also bring back the fact that actually, if you separated out what happened in China, we had one of

our strongest quarters in every other market around the world and with strong double-digit growth. So that's -- those are all dynamics that will have to play themselves out.

. . .

<Q: Mohit Bansal – Wells Fargo Securities, LLC – Senior Equity Analyst> And just trying to understand the long-term growth path for GARDASIL, it seems like, and correct me if I'm wrong, [a lot felt] it would depend on raising awareness in those Tier 1 to 5 cities and male vaccinations. So the question is, of those Tier 1 to 5 cities, where do you think there is bigger opportunity? Because, I mean, going to Tier 4 and 5 could be challenging. And then based on your male vaccination experience in the developed world, how should we think about China in that context?

<A: Robert M. Davis> Yes. So if you look across the Tier 1 to 5 cities, we're actually -- when we quote that we're 30% to 40% penetrated, and again, this is just to the females. ***So this is -- we're only speaking to females right now. We're 30% to 40% penetrated. We're a little bit less penetrated. I think we're on kind of say, 30th percent in the 4- and 5-tier cities, and we're around 40% in the 1 to 3. So there's not a huge spread between the Tier 1 to 3 and the 4 to 5. So we will continue to focus efforts across all of those areas as we have been to date.***

And then it's a whole different exercise to activate the male population across that same area which is, frankly, doesn't -- isn't there today because of the fact that we don't yet have the indication. As you think about how all of this fits into the broader global picture, I think it's also important just to remind everyone that the total penetration of GARDASIL on a global basis to the eligible population is approximately 10%. So our opportunity to activate patients globally as we bring on additional capacity is significant.

And as we've talked about in the past, we were going to continue to look to activate the mid-adult segment in the private market. We're doing that today in Europe, and that's part of when I comment that we're driving double-digit growth across the rest of the world outside of China. Part of it is we are starting to see uptake in that private market

activation, both in Europe and across parts of Latin America and Asia Pacific more broadly.

We're going to continue to drive into the low- and middle-income markets. We see that as a meaningful opportunity going forward, and we are well on our way to getting our costs in a position to be able to compete in that space quite effectively. We will continue to drive that. ***And then obviously, while China is the best example of where we need to get a male indication to drive for gender-neutral vaccination if we truly want to eliminate cervical cancer and increasingly address the other cancers we know related to people with HPV, including head and neck cancers which are very prominent, especially if you look across the Asia Pacific area, that is work we will continue to do***. But not only in China and across Asia, but also across Europe, in other parts of the world where there's still is a lot of opportunity to drive for gender neutral.

And then lastly, Japan is a market where we are continuing to see growth driven by the fact that we've had a renewed NIP program there with both an initial NIP and the catch-up phase and longer term, an opportunity for males there as well. So the opportunities are significant. The context of how we will drive growth has multiple levers for us to look at to do that. ***And that's why we are confident in the $11 billion number long term. And I think that's important as we shape the overall context of the discussion.***

. . .

<Q: Akash Tewari – Jefferies LLC – Equity Analyst> And really helpful color on GARDASIL. Just one more here. Looking at the latest Zhifei contract, it looks like there's around $4.5 billion in potential sales for 2024. That's projected to decline in 2025 and 2026 to around $2.5 billion. Historically, however, it looks like you've always exceeded that contracted figure. So just to be clear, does the contracted decline in sales over the next 2 years bake in the upside for potential male approval? And should we expect the Zhifei contract to get renegotiated as we get further clarity on demand?

<A: Caroline Litchfield> Thank you for the question. ***So the Zhifei contract that we have at this stage is focused on the current approval***

> ***that we have in the market***. So it's really focused on the female population in the age cohort 9 through 45. ***As we move forward and we have a male indication, we will, of course, be working with our partner to have the appropriate doses so that we can protect as many males as possible***.

(Emphasis added).

41. In closing remarks, Defendant Davis pertinently concluded regarding Gardasil as follows:

> . . . But I maybe would close by just bringing back the confidence we see in the business, both in the short term and the long term. ***Obviously, we'll work through what we see happening with GARDASIL in China. But the fact that we see strengthening, and I would call them green shoots around GARDASIL everywhere else in the world, gives us confidence in the $11 billion for that, as we've talked about*** . . .

(Emphasis added).

42. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the alleged false and/or materially misleading statements identified above., In those statements, Defendants continually praised Gardasil's global demand, the opportunity of the eligible population of women in China, the Company's success with consumer activation and education in China, while continually minimizing risks associated with demand, competition, contract minimums, and the impact of China's approval of the 2-dose regimen in early 2024.

43. Investors and analysts reacted immediately to Merck's revelation. The price of Merck's common stock declined dramatically. From a closing market price

of $127.78 per share on July 29, 2024, Merck's stock price fell to $115.25 per share on July 30, 2024, a decline of about 9.78% in the span of just a single day.

44. A number of well-known analysts who had been following Merck lowered their price targets in response to Merck's disclosures. For example, Wells Fargo, while retaining their "equal weight" rating highlighted their concern, stating: "While mgmt. tried to reassure investors by reiterating the >$11B Gardasil guidance for 2030, it does not help when the consensus was $13B. In addition, the mgmt comments including 1) focus on creating awareness and 2) male vaccinations driving future growth create uncertainty around near-term trajectory." The analyst went on to note that "Gardasil China has been and was expected to be a key growth driver for the stock. $2B lower sales in 2030 bring down 2024-30 sales CAGR from 3% to 2.5%."

45. Similarly, Guggenheim, while reducing their price target, cautioned that they were "significantly decreasing our Gardasil ex-US revenue estimates … and this is the main driver of our lower price target for MRK shares." The analyst noted this reduction was based upon "the sudden nature of this news, the low visibility we have into the Chinese market, the long-term importance of Gardasil to MRK's outlook, and a likely near-term competitor entrant into this market next year."

46. The fact that these analysts, and others, discussed Merck's shortfall and below-expectation projections suggests the public placed significant weight on

Merck's prior revenue and sales estimates. The frequent, in-depth discussion of Merck's guidance confirms that Defendants' statements during the Class Period were material.

47. Notwithstanding Defendants' disclosures during the call, they continued to mislead investors by misrepresenting their understanding of the issues surrounding the slowdown in Gardasil vaccinations in China and Merck's partner's, Zhifei's, inflated inventory levels. In doing so, the Defendants deceptively claimed confidence in Gardasil's continued growth in China, both in the existing eligible population of women and the planned expansion following approval for male vaccinations, particularly as it relates to Merk's ability to achieve $11 billion in worldwide Gardasil sales by 2030. Defendants further promoted their efforts to further assist Zhifei by increasing promotional and education efforts to the eligible, targeted population and noted that such efforts, coupled with the reduced shipments, had reduced the overall channel inventory. While Defendants indicated Merck's plan to continue such efforts and maintain similarly reduced shipping levels in the fourth quarter, they made no indication of any further planned cuts to the distribution of Gardasil to China.

October 31, 2024

48. On October 31, 2024, Defendants published their results for the third quarter of fiscal year 2024. During the earnings call that followed, Defendants

discussed the ongoing issues in China but reaffirmed they still believed they would achieve $11 billion in sales by 2030:

> As anticipated, results also reflect a decline in GARDASIL sales year-over-year. Notably, however, we achieved strong double-digit growth for GARDASIL in almost every major region outside of China.
>
> ***In China, consistent with the expectations we discussed on our prior earnings call, we shipped less to our commercialization partner, Zhifei, and we expect fourth quarter shipments will be at a similar level to the third quarter***. Overall channel inventories of GARDASIL have decreased, which is directionally encouraging, while inventory at Zhifei remains above historical levels. ***We are highly focused on this market and are making progress with Zhifei to increase promotional resources and patient education efforts***. We expect these efforts to translate to increased patient activation and demand, but as we've said, this will take time.
>
> Taking a step back, we're proud of the role that GARDASIL is playing in helping prevent certain HPV-related cancers. There's a wide range of long-term growth opportunities around the world due to the tremendous remaining need to protect more individuals, with less than 10% of the global eligible population vaccinated and meaningful opportunities to improve vaccination completion rates, gender-neutral vaccination rates, mid-adult coverage and access in low- and middle-income markets. ***This includes in China, where there is an attractive long-term opportunity, given the significant number of females yet to be immunized and the potential approval for males next year. We're highly focused on using our scale and strong capabilities to drive education and awareness of the benefits of HPV vaccination and to reach and protect more patients globally. As such, we remain confident in our goal of achieving greater than $11 billion of sales by 2030.***

(Emphasis added).

49. A question-and-answer segment followed the Defendants prepared remarks and was heavily focused on discussions surrounding the ongoing issues with

Gardasil in China. For their part, Defendants remained confident in Gardasil's growth potential in the region, as indicated in the following pertinent exchanges:

> <Q: Trung Chuong Huynh – UBS Investment Bank – Analyst> Just on GARDASIL, given the inventory levels remain elevated, you've noted this declining demand. How should we think about dynamics as we head into 2025, given that increase in promotional activity, but that's balanced by the inventory work down? Will you take time? Or do you have any color on when we'll see an inflection to that returning growth?
>
> <A: Robert M. Davis> ***Great. Thanks for the question. Obviously, we're very focused on GARDASIL in China.*** But maybe just to step back for a second, we continue to be very proud of the contribution that GARDASIL is making for patients and people around the world to really address and hopefully eliminate long-term cervical cancer as well as other HPV-related cancers. So that important work will continue. And importantly, as we commented in our prepared remarks, while China did decline, and I'll speak to China in a second, overall, we saw strong double-digit growth in really nearly every other region around the world, which is showing the progress we're making and which is why we continue to have such confidence in the long-term potential for this.
>
> ***But as it relates to China specifically, and as we think about 2025, I don't want to give specific guidance because obviously, we're still working through our 2025 plan. But what I would say is we do expect to continue to see a decline in shipments into China into 2025. And as we had highlighted before, this is happening a little bit earlier than we originally expected. But we had always expected that over time, as we work through the bolus, we would see the female opportunity decline and then hopefully seeing growth come with bringing the male opportunity, which we would expect to see with approval, assuming it comes next year. So that's how we see it progressing.***
>
> ***So as we think about 2025, we see China really in the $2 billion to $3 billion range as far as an opportunity for 2025 and for the next several years with the opportunity in males really being the growth driver. And at that level, we would expect for overall Merck that you're going to continue to see, based on the portfolio we have, solid growth***. So I

think that's just important to kind of frame where we're seeing things but understanding we're focused on this, we're bringing our efforts to drive demand and we're going to make progress. We are making progress, but it's going to take some time.

. . .

<Q: Christopher Thomas Schott – JPMorgan Chase & Co – Senior Analyst> Just another one on GARDASIL. Rob, I believe you said kind of $2 billion to $3 billion per year opportunity for China over the next few years. Just a couple of quick ones there. First, what does that compare to where China is going to shake out for Merck this year? And is that $2 billion to $3 billion number what was reflected in the $11 billion longer-term target?

<A: Robert M. Davis> Yes. So to give you just a sense of where we are, and we don't normally give product-level guidance or specifics on a quarterly basis. But given the importance and focus on GARDASIL, ***just to give you a sense of where we were with China GARDASIL in the third quarter, it's about approximately $500 million in the third quarter. And as we said, we would expect to ship about the same amount in the fourth quarter. So you should expect that the fourth quarter itself would also be in that $500 million range. And so that kind of gives you a sense of where we are***.

So as you look forward to 2025, obviously, as we think in 2025 and over the next several years, if you're running in that $2 billion to $3 billion range, that's why we made the comment that with that and given the other opportunities we see around the world, we remain confident in our ability to get to the $11 billion by 2030. So we are contemplating that $2 billion to $3 billion over the next several years in China as the contribution that it would make to get us to where we need. ***Understanding also that long term, we do expect to be able to have the potential for growth driven by the male opportunity in China*** and then, obviously, continuing to drive more broadly around the rest of the world.

. . .

<Q: Terence C. Flynn – Morgan Stanley – Equity Analyst> Great. Maybe just one question and one clarification. Just on the GARDASIL side, Rob, that's the $2 billion to $3 billion includes the males or it does not include the males? Sorry, I was a little unclear based on the last response . . .

<A: Robert M. Davis> Yes. So I'll take the first part of that question, Terence***. So the answer is yes. the $2 billion to $3 billion over the next several years does include male, but we have the opportunity as you look longer term to drive growth with that opportunity. That was really the point we were trying to make.***

. . .

<Q: Umer Raffat – Evercore ISI Institutional Equities – Senior MD & Senior Analyst of Equity Research> I have -- I wanted to focus on GARDASIL just a little more. That was very helpful commentary, Rob. You mentioned $500 million in sales in 3Q and 4Q to China, which obviously is $2 billion run rate. My question is, was that shipping to demand? Because if so, what that means is inventory sitting at your [indiscernible] is still something that would need to be worked down in 2025 as well as possible 9-valent generic entry -- sorry, 9-valent local competition entry in 2025 as well. How do you factor those 2 dynamics into thinking about the 2025 number of $2 billion to $3 billion in China?

<A: Robet M. Davis> Yes. So if you look at what's happening in the overall marketplace and just to give you a sense, from an inventory perspective, maybe starting there. ***If you look at overall inventory levels in China, they did come down. And that's taking into account, and this is for GARDASIL.*** GARDASIL at Zhifei, which frankly remains high and grew slightly, but that was more than offset by reductions in the CDCs and the points of vaccination. So that's a good sign that we're seeing overall inventories coming down, which also would point to the fact that as we're looking at demand, which we're seeing stabilize, we think we're at a position now whereas we're starting to talk about what we're shipping. ***Our expectation is we are shipping below demand***.

So we have been working very constructively with Zhifei to think about this, both as what we're doing in this year is, frankly, as well as we're

continuing to have constructive dialogue around 2025. ***Our intention would be to balance the need to get product into the marketplace to meet the demand at the same time, allowing for Zhifei to bring down their inventories over time. So we're very thoughtful on how we're thinking about it, and we've done that, taking into account our expectations of both the female competitive launch that could come next year, but also the opportunity that a male approval early next year could allow us to have. So all of those factors are in as we think about that $2 billion to $3 billion number.***

. . .

<Q: Stephen Michael Scala – TD Cowen – MD & Senior Research Analyst> I mean all things considered, is it still possible to see global GARDASIL growth in 2025? And Rob, you noted at the start that recovery in China will take time, but it sounds like you have good visibility now because you're giving this $2 billion to $3 billion guidance for GARDASIL in China. So I'm unclear what it is that we're waiting for.

<A: Robert M. Davis> Well, what we're talking about taking time is basically to work down the inventory and to then build demand over time so that we can continue to drive that market. ***What we're giving you is kind of what we see as the baseline of China. Our hope is that we'll do better.*** And we're going to put the work in to do better and to continue to drive long term. I think that what I'm trying to make sure everyone hears is this isn't going to be solved next quarter. It's going to take us through probably 2025, but we're thoughtful on how we're doing it. We're working with Zhifei in a constructive manner to do it. So those are the elements are going to take time because we need to build the demand. ***We know the opportunity is there with 120 million females still out there to go after and with potentially 200 million males with the male opportunity. We have to activate that demand to make sure we can drive that business***. So that's really what we're focusing on.

As far as it relates to GARDASIL for 2025, I don't think we really want to get into giving product line guidance right now. We were very specific to China because of the concerns that were there. And I wanted to make sure you know that we see solid overall growth for Merck

> because that's important to have context. But beyond that, we normally wouldn't be giving guidance at this point in time.

(Emphasis added).

50. The above statements in Paragraphs 39 to 41 and 48 to 49 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information pertaining to the Company's projected revenue outlook and anticipated growth of Gardasil while also minimizing risks arising from competition to and the approval of reduced dosage regimens. Defendants continued claims that the opportunity in China remained strong, that their newfound ability to provide the vaccine to men could be relied upon to boost demand, that competition was not inhibiting Gardasil's demand, all continued to fall short of the reality of the situation. Despite Merck's claims of worldwide demand and success, the company was simply not positioned to reach the purported $11 billion in Gardasil sales by 2030 without unimpeded growth in China. Defendants misled investors by providing the public with materially flawed statements of confidence and growth projections which did not account for these variables.

The Truth Emerges during Merck's Fourth Quarter Fiscal 2024 Earnings Report

February 4, 2025

51. In the morning of February 4, 2025, Merck published its fourth quarter fiscal year 2024 results, unveiling further declines in worldwide sales and the approval of Gardasil for men in China:

> GARDASIL/GARDASIL 9 Sales Declined 3% to $8.6 Billion; Excluding the Impact of Foreign Exchange; Sales Declined 2%
>
> . . .
>
> Received approval of Gardasil for Males in China, in January 2025.

52. In the Company's 10-K, Merck further noted that the Gardasil "[d]ecline [was] primarily due to lower demand in China, partially offset by higher demand in most international regions, particularly in Japan."

53. Merck held an earnings call shortly after posting the results. During the call, Defendants further discussed the Gardasil setbacks in China, and the impact on the Company's projections overall:

> Now turning to our results and outlook. We delivered strong growth in 2024, reflecting demand for our innovative portfolio . . . We also saw higher demand and achieved strong sales for GARDASIL outside of China.
>
> . . .

As we close out 2024 and entered 2025, the market dynamics for GARDASIL in China have remained challenging. Like many other companies, we've seen increased pressure on discretionary consumer spending, including across the vaccine space more broadly, and ***demand for GARDASIL has not recovered to the level we had expected***. As a result, ***overall channel inventory remains elevated at above-normal levels.***

In light of this and based on further discussions with our commercialization partner, Zhifei, over the past couple of weeks, in particular regarding their most recent financial disclosure and working capital levels, ***we've made the decision to take a new approach and temporarily paused shipments to China beginning this month and through at least midyear. We believe taking this action now more rapid reduction of inventory and help support the financial position of our important and valued partner.***

Importantly, we believe China still represents a significant long-term opportunity for GARDASIL given the large number of females and now males with our recent approval that are not yet immunized. And we remain both committed and well positioned to maximize this potential for the long term. Outside of China, demand for GARDASIL remains robust, and we expect strong growth this year and well into the future.

. . .

Now turning to our 2025 non-GAAP guidance. We expect revenue to be between $64.1 million and $65.6 billion, representing growth [up to 4%], excluding a negative impact from foreign exchange of approximately 2% using mid-January rates. ***For GARDASIL in China, our guidance assumes no further shipments at the low end and less than $1 billion at the high end***. Excluding sales of GARDASIL in China in both 2024 and 2025 and the negative impact from foreign exchange, total company growth is expected to be 7% to 9%.

. . .

Looking at GARDASIL longer term. While we believe there continues to be a path to the $11 billion, we feel it is prudent to withdraw this

> ***target given uncertain timing of an economic recovery in China.*** Our growth expectations outside of China for this important vaccine remain unchanged and and we are well positioned to protect more lives and drive strong growth beyond 2025.
>
> . . .
>
> Next, to vaccines. ***The National Medical Products Administration of China approved GARDASIL to help prevent certain HPV-related cancers and diseases in males 9 to 26 years old.*** In November, at the International Papillomavirus Conference, we presented new clinical and real-world data for GARDASIL 9 that examined the prevalence of oral HPV infection, the burden of HPV-related head and neck cancers as well as rates of HPV infection in females. This evidence reinforces the importance of gender-neutral HPV vaccination with GARDASIL in adults up to age 45.

(Emphasis added).

54. As a result of the disappointing announcements, the Q&A session that followed was heavily focused on the Company's expectations for Gardasil, as discussed in the following pertinent exchanges:

> <Q: Mohil Bansal – Wells Fargo Securities, LLC – Senior Equity Analyst> Sorry, I joined a little bit late, but if the question -- have you commented on how much inventory Zhifei had at this point with GARDASIL? And would the decision to stop shipment, possible shipments for first half, would take care of the inventory? I'm just trying to get -- understand the demand situation in China, sir.
>
> <A: Robert M. Davis> Yes. Mohit, thanks for the question. We have not commented specifically on how much inventory Zhifei is sitting on. They're a public company, so we need to leave it to them to make comments about that. But I think the important point here is to understand that as we've seen the marketplace, what we intend to is to accelerate that drawdown. So we are planning to ship and by -- frankly, by not shipping February potentially through the midyear and essentially longer, depending on how we see the inventory come down,

we're going to allow the underlying demand that is still there to absorb the Zhifei inventory and improve Zhifei's financial position and working capital.

We think if we can put the inventory situation behind us, we can get to a more normal market dynamic, one where with the underlying demand and the fact you have the male indication coming, it can come back to growth. So the speed with which we burn that down, we'll have to see.

But the other thing I would just highlight for context, with this rebasing, GARDASIL China now is about 1% of our total earnings. So it is becoming -- of our total revenue. So obviously, that's an important thing to understand. And that's why we also highlighted that if you look at the way the business is going to progress, as we get into the back half of this year and we anniversary the GARDASIL China situation, we will be strong growth and -- for overall more -- as well as, as we go into '26 and '27. And that's important because, obviously, at that point, anything that happens in China with GARDASIL is an upside. And that's really why we've decided to now rebase this, understanding it's a change from the direction we had taken previously.

. . .

<Q: Geoffrey Christopher Meacham – Citigroup Inc. – Managing Director> Sorry to continue to harp on GARDASIL. But just, I guess, given the situation in China, you guys are less willing to predict the timing of recovery. But I guess the question, Rob, is there an inventory threshold that you need to see to start shipping again? I wasn't sure what the -- what kind of the tipping point would be for that. And maybe more broadly, just given the political climate towards vaccines overall, maybe just talk about where this TA falls in your BD or internal R&D priorities, if that's changed at all?

<A: Robert M. Davis> Yes. Geoff, thanks for the comments. So on China, in particular, there's not a -- I don't want to commit to a specific inventory level. Obviously, we need to see it come down meaningfully from where it is. And I think by taking this action, to stop shipments given the demand that's there, we're going to see that happen. We just have to let it work itself through. Because the economy there still is soft,

and that has led to the fact that we are seeing consumer demand continue to be weak.

And so as that situation resolves, I think that will determine the speed with which all of this happens. But I think it's important to just reemphasize, going forward, by rebasing this now out, this is upside. This is not a core to our growth story going forward. And so that is also what we want to make sure people understand. I recognize it's a big change. And we want to do and we will do everything -- we are very committed and positioned well to drive growth in China. But to me, at this point, that will be upside for the company. And beyond that, the breadth of what we have will drive the growth in oncology, in Animal Health and with our new launches.

To the vaccines business more broadly, we continue to believe in vaccines as an important area. Obviously, we have CAPVAXIVE, which is launching as we speak. We have plazrobumab, a monoclonal antibody for RSV, that we hope to get approval and see come before the RSV season this year. And then we have other programs in development, including dengue is probably one of the most significant other ones.

So we continue to focus there. I wouldn't say that vaccines is a big focus of our BD strategy primarily because we just haven't seen that many opportunities in the space. But we are continuing to be committed to driving the R&D we're doing in this space going forward and continue to believe there's opportunity for it.

. . .

<Q: Christopher Thomas Schott – JPMorgan Chase & Co – Senior Analyst> Another one on GARDASIL. Specific to the long-term guidance, I totally understand the near-term dynamics need to reduce inventory, but the removal of the $11 billion target is -- how much of this is conservatism just given the dynamics of China versus this being a more permanent reset of your view on the Chinese market? I'm trying to get my hands around that. And then as part of that answer, maybe just talk about GARDASEL ex China. Has there been any change in your longer-term views on the global opportunity ex China for the product?

<A: Robert M. Davis> Yes. No, thanks for the question, Chris. So as you look at China, as Caroline said in the prepared remarks, we continue to believe there's a path to the $11 billion, but feel it's prudent really to withdraw the target right now because it is uncertain, both the timing of the recovery in China and the extent.

That being said, if you look at the underlying dynamics that had always caused us to believe in the growth in China, they're still there. We still have the 100 million-plus women, 120 million women who have yet to be vaccinated in the Tier 1 to 5 cities. We have the male indication where we are the only company with that indication, and we're launching that as we speak. And obviously, that is a population about the same size as female. It's about 200 million if you look in the total potential once we're in that marketplace. So the opportunity is there.

We have the near-term dynamics of the inventory and the near-term dynamics of the economy we need to adjust. That is why I think it's prudent to just say until we see that, because China was a meaningful part of the $11 billion, that's why we made the decision to say, let's pull back on the $11 billion.

As we look at every other market around the world, for the rest of the world, our view remains unchanged. And as Caroline pointed out, if you exclude GARDASIL China, we had strong double-digit growth this year, again, in the rest of the world. And as we look forward, if you exclude China, we have strong growth coming in GARDASIL every year, year-on-year.

So nothing has changed in our long-term view. We need to get the China situation figured out. ***We need to lap this market dynamic and figure out what the actual growth and opportunity is in China. And until we do that, I just want to remove this from the dialogue because by continuing to always come back to this, I feel like we missed so much else we have in the strength of our pipeline and in the growing breadth of our business***. That is really the fundamentals of our growth long term, has been and will continue to be. And I want to get people focused there because that's where we're focused.

(Emphasis added).

55. The aforementioned press releases and statements made by the Individual Defendants contradicted their earlier statements, including those made during the July 30, 2024, and October 31, 2024, earnings calls. During those calls, the Defendants portrayed an understanding of the issues surrounding Gardasil's slowdown in China, wherein they disclosed Zhifei's inflated inventory, presented a plan to reduce shipments to allow Zhifei to reduce the inventory backlog, and announced that such inventories were deflating as the company was purportedly shipping below demand levels.

56. Investors and analysts again reacted promptly to Merk's revelations. The price of Merck's common stock declined dramatically. From a closing market price of $99.79 per share on February 3, 2025, Merck's stock price fell to $90.74 per share on February 4, 2025, a decline of more than 9% in the span of just a single day.

57. A number of well-known analysts who had been following Merck lowered their price targets in response to Merck's disclosures. For example, UBS, while cutting their price target 12.5%, highlighted that "communication around (and management of) Gardasil has been uncerwhelming and overshadowed the name. We have now experienced three back-to-back quarters of disappointing results primarily driven by weak HPV vaccine demand in China which understandably frustrates investors and is reflected in the >$100bn market cap erased from MRK." The analyst

continued, "with the bottom end of guide contemplating no shipments to China as a worst case scenario we see Gardasil as relatively washed out at current trading levels."

58. The fact that these analysts, and others, discussed Merck's shortfall and further reduced projections suggests the public placed significant weight on Merck's statements of prior confidence in the existence of and their ability to capitalize upon demand for Gardasil in China. The frequent, in-depth discussion of Merck's guidance for Gardasil confirms that Defendants' statements during the Class Period were material.

Loss Causation and Economic Loss

59. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Merck's common stock and operated as a fraud or deceit on Class Period purchasers of Merck's common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Merck's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Merck's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

60. Merck's stock price fell in response to the partial corrective event on July 30, 2024, as alleged supra. On July 30, 2024, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Merck's forecasting processes and growth guidance.

61. In particular, on July 30, 2024, Merck announced a significant reduction of the sale of Gardasil in China and reduced their own prior expectations for shipments of the vaccine to Zhifei, Merck's distributor of Gardasil in China, for the remainder of 2024. Notably, however, Merck refrained from walking back their long-term projections for Gardasil.

62. Merck's stock price again fell in response to the final corrective event on February 4, 2025, as alleged supra. On February 4, 2025, Defendants disclosed additional information that was directly related to their prior misrepresentations and material omissions concerning Merck's forecasting process and growth guidance both prior to and following the July 30, 2024, partial corrective event.

63. In particular, on February 4, 2025, Merck announced that it would entirely cease shipments of Gardasil to China "through at least midyear" and withdrew their long-standing projection to achieve $11 billion in Gardasil sales worldwide by 2030.

Presumption of Reliance; Fraud-On-The-Market

64. At all relevant times, the market for Merck's common stock was an efficient market for the following reasons, among others:

(a) Merck's common stock met the requirements for listing and was listed and actively traded on the NYSE during the Class Period, a highly efficient and automated market;

(b) Merck communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(c) Merck was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Merck was reflected in and incorporated into the Company's stock price during the Class Period.

65. As a result of the foregoing, the market for Merck's common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Merck's stock price. Under these

circumstances, all purchasers of Merck's common stock during the Class Period suffered similar injury through their purchase of Merck's common stock at artificially inflated prices, and a presumption of reliance applies.

66. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

67. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with revenue projections while at the same time failing to maintain adequate forecasting processes. Defendants provided the public with forecasts that failed to account for this decline in sales and/or adequately disclose the fact that the Company at the current time did not have adequate forecasting processes.

68. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

69. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Merck who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

70. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who

purchased or otherwise acquired Merck's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

71. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Merck's common stock were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Merck or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. October 31, 2024, there were approximately 2.53 billion shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

72. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

73. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

74. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Merck;

(c) whether the Individual Defendants caused Merck to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of Merck's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

75. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Against All Defendants for Violations of

Section 10(b) and Rule 10b-5 Promulgated Thereunder

76. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

77. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

78. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Merck common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Merck's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

79. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Merck's securities. Such reports, filings, releases and statements were materially false and

misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

80. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

81. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of Merck's internal affairs.

82. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-

held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Merck's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Merck's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Merck's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

83. During the Class Period, Merck's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Merck's common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases

and/or acquisitions by Plaintiff and the Class, the true value of Merck's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Merck's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

84. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

85. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants

for Violations of Section 20(a) of the Exchange Act

86. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

87. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly

and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about Merck's misstatements.

88. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Merck which had become materially false or misleading.

89. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Merck disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Merck to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Merck's common stock.

90. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to

direct the actions of, and exercised the same to cause Merck to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

91. By reason of the above conduct, the Individual Defendants and/or Merck are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: February 12, 2025

Respectfully submitted,

LEVI & KORSINSKY, LLP

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